



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,640	12/02/2003	Eric Cossement	2003_1709	2005
513	7590	11/22/2004	EXAMINER	
WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			BERNHARDT, EMILY B	
		ART UNIT	PAPER NUMBER	
		1624		
DATE MAILED: 11/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,640	COSSEMENT ET AL.	
	Examiner Emily Bernhardt	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 September 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 9-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 9-14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

In view of applicants' response filed 9/7/04 the following still applies.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Baltes (US'358) and applicants' own admission for reasons given previously.

Applicants continue to urge patentability based on their process of making instant compounds vs prior art process. Claims herein are not to a process of making but rather to compounds, compositions, and uses. Only one process of making is needed to make 102/103 rejections and this need not be the best process. However, the optical purity reported in GB'321 for both levo- and dextrorotatory products derived from optical starting material of formula (III) is high (95%) not low. See discussion on p.10, example 3. Purer forms (98% vs 95%) do not necessarily defeat obviousness as was decided by Volwiler, previously cited. Additionally, the teachings of GB'321 is not limited to just resolution via tartaric acid. See p.3.

With regard to applicants' remark made on p.3 of the response, the examiner never required a showing between instant isomers but rather only with prior art

racemate which is needed to consider patentability for each of the claimed isomers as mandated by case law previously cited.

Appellants rely on data set forth in the specification on p.29 for instant isomers, identified as K and L therein . While one of the pair (the dextro) was shown to be devoid of unwanted side effects such as sedation and the other to be useful as a more potent histamine inhibitor for topical use, the showing does not address the thrust of the rejection over Baltes since it compares the activities of the (+) and (-) isomers and not the prior art racemate. Note any such showing with the racemate v. the individual isomers must demonstrate superior and unexpected results over the racemic product. Note the case law on optical isomers in previous action. It was pointed out to applicants in earlier parent (09/087808) that Baltes teaches the corresponding racemate identified as B in the US patent in col.13 as also devoid of a sedative effect and for various forms of administration including in unguents and creams which are the same carriers relied on herein for topical use. Urging the racemate's activity is a composite of the activities of the 2 optical isomers is suggestive of expected not unexpected results. Note in particular In re Adamson on p.235, right column regarding results between racemates and claimed isomers on appeal therein.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Application/Control Number: 10/724,640
Art Unit: 1624

Page 5

E Bernhardt
Emily Bernhardt
Primary Examiner
Art Unit 1624